IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, v. ADARSH GUPTA	Hon. Madeline Cox Arleo CRIMINAL NO. 2:20-cr-00773

MEMORANDUM OF LAW IN SUPPORT OF
DEFENDANT'S MOTION TO DISMISS THE INDICTMENT

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I. INTRODUCTION

Defendant Adarsh Gupta ("Dr. Gupta") is a professor and attending physician in the Department of Family Medicine at the Rowan University School of Osteopathic Medicine, where Dr. Gupta has practiced since he received his medical degree in 2000. In his twenty years of clinical practice and seventeen years of teaching, Dr. Gupta has consistently excelled: Dr. Gupta is well-reviewed by his patients; he has published numerous articles in peer-reviewed journals and written book chapters in medical textbooks; he has won numerous teaching awards; and he has presented nationally and internationally on various medical topics. In late 2017, Dr. Gupta began working part time for a telemedicine company called "AffordADoc," providing telehealth consultations to patients by telephone. In the course of that work, Dr. Gupta prescribed, among other things, orthotic braces for geriatric patients. This case concerns the brace prescriptions Dr. Gupta wrote.

Counts 1-4 of the Indictment ("Indictment") charge Dr. Gupta with healthcare fraud by fraudulently prescribing orthotic braces based on his telephone consultations with patients. The Indictment, however, is fatally defective because it relies on Local Coverage Determinations ("LCDs")—which have no legal effect—to establish that the telephone consultations without an in-person medical examination render the brace claims ineligible for payment and, therefore, false (the "LCD Fraud theory"). Contrary to this LCD Fraud theory, the binding Medicare regulations *permitted* brace prescriptions without an in-person physical exam. Accordingly, the LCD fraud theory conflicts with the law and cannot state an offense.

Moreover, under traditional fraud analysis, the Indictment fails to allege the critical elements of: (1) a material deception and (2) that the deception contemplated economic harm. Because the LCD fraud theory permeates the Indictment, and the Indictment otherwise fails to

allege the critical element of material deception (Count 1), or any facts showing a material deception, or that the deception was intended to cause any concrete economic harm (Counts 1-4), the Indictment should be dismissed.

Lastly, premising a criminal case on an expert opinion about a disputed medical standard, *i.e.* that the standard of care requires that braces can only be prescribed after an in-person examination, conflicts with the law and thereby deprives Dr. Gupta of Due Process. This fraud theory fails to provide Dr. Gupta (or any other doctor) with fair notice of what degree of difference in medical opinion is or is not criminal. In sum, the Indictment should be dismissed as a matter of law as a violation of LCDs is not a violation of federal criminal law, nor can a federal crime be based upon a disputed medical standard of care.

For the foregoing reasons, this Court should dismiss the Indictment against Dr. Gupta. In the alternative, Dr. Gupta requests that the Court grant Dr. Gupta's accompanying Motion for Disclosure of Grand Jury Materials and further grant Dr. Gupta leave to supplement this motion accordingly.

II. ARGUMENT

A. THE STANDARD FOR A MOTION TO DISMISS

Generally, the sufficiency of an Indictment rests on whether the charge includes "a plain, concise and definite written statement of the essential facts constituting" the crime (here, the conspiracy and healthcare fraud counts under 18 U.S.C. §§ 1035, 1347, and 1349), and accordingly, whether each count is in compliance with FED. R. CRIM. P. 7(c) and the Fifth and Sixth Amendments. *United States v. Rankin*, 870 F.2d 109, 112-13 (3d Cir. 1989). In addition to providing a defendant with constitutional notice of the charges and preventing him from being put in jeopardy twice, the rules preserve the protection provided by the Fifth Amendment that a

defendant only answer to a crime upon indictment of a grand jury. *United States v. Silverman*, 430 F.2d 106, 110 (2d Cir. 1970), *cert. denied*, 402 U.S. 953 (1971).

The rationale for this constitutionally mandated rule is that a defendant should not be convicted on the basis of facts not found by or even presented to the grand jury which indicted him. *Russell v. United States*, 369 U.S. 749, 770 (1962). Although the statutory language may be used as a general description of the offense, there must be specific facts so as to inform the accused of the nature of the offense. In *Hamling v. United States*, 418 U.S. 87 (1974), the Court emphasized that the statutory language "must be accompanied with such a ***statement of the facts and circumstances*** as will inform the accused of the specific offense, coming under the general description, with which he is charged." *Id.* at 117-18 (emphasis added).

Of course, the Indictment must state all the material elements of the offense, including any judicially imported element. *See United States v. Tykarsky*, 446 F.3d 458, 474 (3d Cir. 2006); *United States v. Foley*, 73 F.3d 484, 488 (2d Cir. 1996); *United States v. Yefsky*, 994 F.2d 885, 893-94 (1st Cir. 1993). A court must find that "a charging document fails to state an offense if the specific facts alleged in the charging document fall beyond the scope of the relevant criminal statute, as a matter of statutory interpretation." *United States v. Panarella*, 227 F.3d 678, 685 (3d Cir. 2002).[1] A court is entitled to entertain a motion to dismiss under FED. R. CRIM. P. 12(d) where the underlying facts are essentially undisputed and a legal determination can be made as to the applicability of an element of the offense. *Id.* "It is permissible and may be desirable where the facts are essentially undisputed, for the district court to examine the

[1] *See also United States v. Schiff*, 602 F.3d 152, 162-66 (3d Cir. 2010) (indictment alleging "failure to rectify misstatements of others" does not, as a matter of law, state an offense under securities statute that criminalizes omissions of information); *Gov't of V.I. v. Greenidge*, 600 F.2d 437, 438-40 (3d Cir. 1979) (indictment alleging assault on male companion of rape victim does not, as matter of law, state offense under statute that criminalizes assaulting rape victim).

factual predicate for an Indictment to determine whether the elements of the criminal charge can be shown sufficiently for a submissible case." *United States v. Brown*, 925 F.2d 1301, 1304 (10th Cir. 1991); s*ee also United States v. Yakou*, 428 F.3d 241 (D.C. Cir. 2005); *United States v. Risk*, 843 F.2d 1059 (7th Cir. 1988). As explained in *United States v. Lott*, 309 F.2d 115, 117 (5th Cir. 1962), *cert. denied*, 372 U.S. 920 (1963), the offense must be accurately described in an indictment and the allegations expanded beyond the words of the statute in order to embrace all the ingredients necessary to the offense.

B. THE INDICTMENT

Counts 1-3 of the Indictment charge Dr. Gupta with engaging in a conspiracy to commit healthcare fraud and engaging in a healthcare scheme to defraud Medicare in violation of 18 U.S.C. §§ 1349 and 1347. *See* Indict. at ¶¶1-9. Count 4 charges false statements relating to healthcare matters in violation of 18 U.S.C. § 1035. *See id.* at ¶¶10-11.

Specifically, the Indictment alleges that Dr. Gupta contracted with AffordADoc to provide telehealth consultations, for which he was paid "$30 per patient consultation." *See id.* at ¶¶1a and 4b. In the course of that work, Dr. Gupta prescribed, among other things, orthotic braces "without a physical examination" purportedly in violation of LCDs. *Id.* ¶¶1o and 4f.

The Indictment further alleges that AffordADoc "and others solicited illegal kickbacks and bribes from brace suppliers for brace orders that were signed by" Dr. Gupta and other doctors. *Id.* at ¶4d. The brace orders allegedly procured through illegal kickbacks and bribes "were forwarded to [brace] suppliers for fulfillment," which then "submitted and caused the submission of claims to Medicare" based on those orders. *Id.* at ¶4g. Notably, the Indictment ***does not charge*** Dr. Gupta with conspiracy to pay or receive illegal kickbacks and ***does not allege*** that Dr. Gupta even knew about AffordADoc's kickback scheme with the brace suppliers.

See id. ¶4d. The Indictment also does not allege that Dr. Gupta failed to adequately review each patient's medical history or failed to actually consult with each patient before writing any brace prescription. *See id.* at ¶4f.

Rather, the Indictment cites an LCD pertaining to knee braces, LCD L33318, which purports to "***require***[] an in-person examination of the patient" because "knee braces were medically necessary ***only*** where knee instability was documented by an in-person examination of the beneficiary and objective description of joint laxity (*e.g.*, varus/valgus instability, anterior/posterior Drawer test)." *Id.* at ¶1o (emphasis added). Based on this LCD, the Indictment contends that "[c]laims were not reasonable and necessary if only pain or a subjective description of joint instability were documented." *Id.* The Indictment then alleges that Dr. Gupta "ordered braces that were medically unnecessary, for patients with whom he lacked a pre-existing doctor-patient relationship, ***without a physical examination***, and frequently based solely on a short telephonic conversation with the beneficiary"—contrary to the LCD. *Id.* at ¶4f (emphasis added). The Indictment also recites another LCD pertaining to back braces. The provisions of that LCD purports to require that back braces only be prescribed for four specific purposes. *See id.* at ¶1p. The Indictment, however, does not allege that any back-brace prescriptions were not prescribed by Dr. Gupta for one of those four reasons.[2]

The Indictment then alleges that Dr. Gupta "and others" caused DME companies to submit false and fraudulent claims for brace orders in excess of $5.4 million. *See id.* at ¶4j. And in describing in the "manner and means" of the alleged scheme to defraud Medicare, the

[2] The Indictment also notes the Medicare Part B regulations regarding coverage for telehealth services. *See id.* at ¶1s. But the Indictment then admits that those regulations "did not prohibit ordering DME where the consultation itself was not billed to Medicare" and that "[n]either [Dr. Gupta] nor the AffordADoc Network billed Medicare for telemedicine consultations with beneficiaries." *Id.* at ¶¶1t and 4d.

Indictment claims that Dr. Gupta prepared "false and fraudulent" clinical documentation in patient files and brace orders. *Id.* at ¶4i. But it does not allege any specific facts in any patient's medical history or consultation with Dr. Gupta that show the brace prescriptions were medically unnecessary. Instead, the Indictment leaps to that conclusion based solely on alleged defects in the process leading to the prescription—specifically, that: (i) based on Dr. Gupta's telephone consultations, the prescriptions of braces were not "medically necessary"; (ii) he did not perform a "medical examination"; and (iii) he recommended to the patient that they continue medical follow-up as part of an on-going plan of care "when he knew he had not done so." *Id.* In sum, the alleged "fraudulent" nature of the claims is based solely upon Dr. Gupta's failure to perform a hands-on medical examination in violation of the LCD (*Id.* at ¶4i(i) and (ii)) and that his documentation in the patient medical records that he recommended medical follow-up to the patient was false.

C. THE LCD FRAUD THEORY DOES NOT CHARGE AN OFFENSE

The Government predicates its fraud charges against Dr. Gupta on its assertion that LCD L33318 "***required*** an in-person examination of the patient," that "knee braces were medically necessary ***only*** where knee instability was documented by an in-person examination of the beneficiary," and that "[c]laims were not reasonable and necessary if only pain or a subjective description of joint instability was documented." Indict. at ¶1o (emphasis added). The Government's argument then follows that—because Dr. Gupta did not conduct "an in-person examination of the patient"—his knee brace prescriptions were invalid, rendering the knee braces medically unnecessary (and thus not reimbursable), which then rendered the claims "false" as a matter of law. According to the Indictment, the alleged false documentation in the patient medical records was designed to conceal the fact that Dr. Gupta did not physically

examine the patients as required by the LCD. *See id.* at ¶¶4f, 4i(ii). Because this LCD Fraud theory is based solely upon Dr. Gupta's violation of the LCD provision requiring that "[f]or codes L1832, L1833, L1843, L1845, L1850, L1751 and L1852, knee instability must be documented by the examination of the beneficiary and objective description of joint laxity (e.g., varus/valgus instability, anterior/posterior Drawer test)," the Indictment does not charge an offense. This is because: (1) the LCDs have no binding legal effect, and (2) the LCDs directly conflict with controlling Medicare regulations that permit prescribing and billing for braces without any in-person physical examination.

First, contrary to the Government's assertion, LCDs do not, in fact, create any legal prerequisite to a clinical finding of medical necessity. LCDs are not binding rules or regulations promulgated by CMS or any other government agency. Rather, LCDs are merely unilateral decisions made by an independent, third-party private contractor ("Medicare Administrative Contractor" or "MAC") regarding its own internal policy as to whether or not to cover a particular item or service in its geographic jurisdiction. *See* 42 U.S.C. § 1395ff(f)(2)(B). As such, it is well-established that an LCD (and any "requirement" set forth therein) "binds only the contractor that issued it, and only at the initial stages of the Medicare claim review process." *Porzecanski v. Azar*, 316 F. Supp. 3d 11, 15 (D.D.C. 2018); *see, e.g.*, *Odell v. Azar*, 344 F. Supp. 3d 1192, 1197 (D. Nev. 2018) ("Only the MAC that created the LCD is bound by it and LCDs 'are only binding in the initial adjudication and during the preliminary appeals stages.'") (quoting *Erringer v. Thompson*, 371 F.3d 625, 634 n. 10 (9th Cir. 2004)); *United States ex rel. Hartpence v. Kinetic Concepts, Inc.*, No. CV081885CASAGRX, 2018 WL 7568678, at *1 (C.D. Cal. July 30, 2018) ("[A] DMAC may promulgate [an LCD], which is that DMAC's own determination as to whether a particular item or service is considered reasonable and necessary

within its geographic jurisdiction. CMS does not issue or approve LCDs, which are not binding on other contractors or in administrative proceedings or federal courts.").

Indeed, if a contractor initially denies Medicare coverage on the basis of an LCD, that denial can be appealed—first to the MAC itself through submission of a request for redetermination pursuant to 42 C.F.R. § 405.940, next through submission of a request for reconsideration to a qualified independent contractor ("QIC") pursuant to 42 C.F.R. § 405.960, then through submission of a request for *de novo* hearing before an Administrative Law Judge ("ALJ") pursuant to § 405.1002, then to the Medicare Appeals Council pursuant to § 405.1100, and ultimately to a federal judge. In this five (5) step appeals process, neither the QIC, the ALJ, the Medicare Appeals Council, nor the federal court are bound by the LCD, and any of them could have concluded that the billed-for device was, in fact, medically reasonable and necessary—*notwithstanding a provision in any LCD*. *See* 42 U.S.C. § 1395ff(c)(3)(B)(ii)(II); 42 C.F.R. § 1062(a); *Porzecanski*, 316 F. Supp. 3d at 20 ("[A]lthough a local coverage determination may direct how ***contractors*** process certain billing codes, *it cannot obviate the duty of administrative law judges and this Court to determine what the Medical statute [actually] requires*."). This is not some hypothetical. Where a provision of an LCD conflicts with the binding coverage provisions of the Medicare statute and regulations, medical providers remain obligated to provide covered services to the Medicare beneficiary. Where statutorily covered medications, devices, and services are denied due to a provision in an LCD,

providers are entitled to challenge such a determination and in many cases they prevail on appeal.[3] Regardless of the ultimate result, the fact that these medical providers may have prescribed and billed for something contrary to an LCD ***does not***, *ipso facto*, mean that the prescriptions were defective, that the item or device supplied was medically unnecessary, or that the bills for the item provided as a result of the prescription were fraudulent or otherwise ineligible for payment. *Cf. United States v. AseraCare, Inc*., 938 F.3d 1278, 1288 (11th Cir. 2019) ("The district court correctly stated . . . that the LCDs are 'eligibility guidelines' that are not binding and should not be considered 'the exact criteria used for determining' terminal illness. ***As such the jury was not permitted to conclude that Dr. Liao's testimony was more credible because he made reference to the LCD criteria, or that AseraCare's claims were false if they failed to conform to those criteria***.") (emphasis added).

More importantly, the Government's reliance on LCDs here to *require* a face-to-face medical examination of the patient before prescribing braces and as a prerequisite to payment *conflicts with the law*. The operative and legally binding Medicare regulations *permit* prescribing knee braces (and other braces) without a face-to-face examination. Specifically, 42 C.F.R. § 410.38(g)(2)(i)[4] requires Medicare to publish a list of designated durable medical

[3] *See, e.g.*, *Porzecanski*, 316 F. Supp. 3d at 16 ("Relying on a local coverage determination, the initial contractor Novitas Solutions and the qualified independent contractor Maximus Federal Services rejected Porzecanski's claims for IVIG treatments received in November 2015, December 2015, and January 2016. Administrative law judges, however, reversed the contractors in early 2017."); *In the Case of United Healthcare Claim for Medicare Advantage Benefits 1-6644301*, Docket No. M-11-758, 2011 WL 6960539, at *3 (H.H.S. June 3, 2011) (finding that beneficiary was entitled to Medicare coverage of a SmartVest, a type of high frequency chest wall oscillation device, notwithstanding a contrary LCD (LCD L12934)).

[4] CMS amended Section 410.38 on November 8, 2019, effective January 1, 2020. The amended version of this Section still requires that CMS publish a list of specific DME items that require a face-to-face encounter, but this requirement is now found at subsection (c)(8), rather than at subsection (g)(2)(i).

equipment ("DME") items ("Specified Covered Items") that require, as a condition of payment, a face-to-face encounter. It is significant that the applicable list[5] *does not include* any knee or back braces, reflecting Medicare's determination that a face-to-face encounter is not necessary for the prescription of these braces (or other braces)—an agency determination with the force of law and to which the LCDs must yield. In other words, because the LCD conflicts with governing Medicare regulations, the LCDs are invalid and cannot operate to create a condition of payment not found in the law. Thus, the LCDs cannot possibly serve as proof that the braces should not have been covered by Medicare or that Dr. Gupta's clinical determinations of medical necessity and resultant prescriptions were wrong, let alone fraudulent or criminal. However, that is exactly what the Government is trying to do here—not only basing its criminal prosecution on an alleged violation of an LCD, but on one that is contrary to binding Medicare regulations.

Bringing a criminal enforcement action based on a violation of the LCDs would not only be legally impermissible, it would also be inconsistent with Department of Justice policy. The January 25, 2018 Memorandum regarding "Limiting Use of Agency Guidance Documents in Affirmative Civil Enforcement Cases" issued by the Associate Attorney General provides that "the Department may not use its enforcement authority to effectively convert agency guidance documents into binding rules. Likewise, Department litigators may not use noncompliance with guidance documents as a basis for proving violations of applicable law in ACE cases." Reliance on the LCD in the instant case would be even a step farther. Here, the Government would be using noncompliance with guidelines issued by a private, third-party contractor as a basis for

[5] The applicable version of that list is available at: https://wayback.archive-it.org/2744/20201010110721/https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/FacetoFaceEncounterRequirementforCertainDurableMedicalEquipment (10/10/2020).

proving a violation of applicable law in a criminal case. Put another way, if the DOJ cannot use non-compliance with guidance documents from a government agency to prove a civil violation, the DOJ certainly cannot use guidance from a private party contractor as the foundation for a criminal case.

In sum, this LCD Fraud theory permeates Counts 1 through 4 of the Indictment, as it is the key premise for establishing that Dr. Gupta's brace prescriptions, including those specifically identified in Counts 2 - 4, were "medically unnecessary" and, therefore, false. But because noncompliance with an LCD—particularly when it conflicts with governing Medicare regulations as LCD they do here—cannot prove that a claim is not reimbursable or not medically necessary, let alone false or fraudulent, the Indictment fails to charge an offense as a matter of law.

D. THE INDICTMENT FAILS TO CHARGE THE ELEMENT OF MATERIAL DECEPTION OR THAT ANY DECEPTIVE CONDUCT WAS DESIGNED TO CAUSE A PROPERTY LOSS

In both traditional fraud prosecutions as well as healthcare fraud prosecutions, a properly pleaded indictment of a criminal scheme or artifice to defraud must allege both a material deception and that the deceptive conduct was intended to cause a property loss. Although the courts have found that the federal fraud statutes are broad, the jurisprudence requires that the deceptive conduct underlying the scheme to defraud be "material." *Neder v. United States*, 527 U.S. 1, 20-25 (1999). In *Neder*, the Court found that Congress intended to adopt the common-law requirement that deception, in order to constitute fraud, must be material. *Id.* at 22-23. After *Neder*, the courts analyzing healthcare schemes to defraud only find material deception when the misstatement is capable of inducing payment by Medicare. *See United States v. Advantage Medical Transport Inc.*, 251 F. App'x 258, 262 (3d Cir. 2018) (materiality of false statements

under § 1035 only if they would "naturally tend to influence Medicare's decision-making authority when issuing reimbursements"); *United States v. Palin*, 874 F. 3d 418, 421 (4th Cir. 2017) (materiality is an element of health care fraud and conspiracy to commit that offense); *see also United States v. Radetsky*, 535 F.2d 556, 572 (10th Cir. 1976), *overruled on other grounds by United States v. Daily*, 921 F.2d 994 (10th Cir. 1990)[6] (misstatement to Medicare not capable of inducing payment is immaterial).

Moreover, the Government must show that, in connection with the deception, "some actual [economic] harm or injury was contemplated by the schemer." *United States v. Regent Office Supply Co.*, 421 F.2d 1174, 1180 (2d Cir. 1970); *United States v. Starr*, 816 F.2d 94, 98 (2d Cir. 1987); s*ee United States v. Menon*, 24 F.3d 550, 556 (3d Cir. 1994) (noting that intent to defraud generally requires intent to deprive someone of property or money). Because the defendant must intend to harm the fraud victim's economic interest depriving them of a property right, "misrepresentations amounting only to a deceit are insufficient to maintain a mail or wire fraud prosecution." *Starr*, 816 F.2d at 98. The deceit must be coupled with a contemplated harm to the victim's property interests. *See id.* In sum, where rights are involved "whose violation would lead to no concrete economic harm," there can be no fraud offense. *United States v. Asher*, 854 F.2d 1483, 1493 (3d Cir. 1980) (mail fraud). This Circuit has adopted this proposition generally in healthcare fraud cases. *See United States ex. rel. Petratos v. Genentech Inc.*, 835 F.3d 481, 487 (3d Cir. 2017) (claim is false "if it does not comply with the statutory conditions for payment").

[6] *Daily* held, contrary to *Radetsky*, that the issue of materiality was a question of law. *Daily*, 921 F.2d at 1004. But that holding was, in turn, overruled by *United States v. Gaudin*, 515 U.S. 506 (1995). *See, e.g., United States v. Wiles*, 102 F.3d 1043, 1054 (10th Cir. 1995), *vacated on other grounds sub nom United States v. Schleibaum*, 522 U.S. 945 (1997).

First, although the Indictment charges generally that the scheme was intended to defraud Medicare, (*see* Indict. at ¶ 4j), the judicially imported element of "materiality" is not specifically alleged in Count One. While the failure to allege this element may not be fatal, the court must examine whether the indictment alleges "facts that would warrant an inference of materiality." *United States v. Chalker*, No. 12-cr-0367, 2013 WL 4547754 at *5 (E.D. Pa. Aug. 23, 2013). Here, there are no facts alleged that could amount to material misrepresentation or deception that could influence Medicare's payment decision.[7]

Apart from the LCD Fraud theory, the Indictment does not allege any facts showing that any false statements made in the clinical documentation were material to Medicare's decision to pay a brace claim. The only facts alleging falsity appear in paragraph 4(i), which alleges that Dr. Gupta falsely claimed he performed an in-person "medical examination," and that Dr. Gupta falsely claimed he recommended to the patient they continue "medical follow-up." But these alleged deceptions are not conditions of payment and not capable of influencing the Medicare payment decisions as a matter of law.

As explained above, the Medicare regulations allow for prescriptions of braces without any in-person physical examination by a doctor, *see supra* Section II.D; thus, whether or not Dr. Gupta performed an in-person physical examination cannot influence Medicare's payment decision. Indeed, the Indictment concedes that Dr. Gupta prescribed braces based on his telephone consults with patients. *See* Indict. at ¶4f. And telephone consults are expressly

[7] Although the Indictment does charge "materiality" in Counts Two through Four, there are no facts to establish why the deceptive conduct was material other than the failure to comply with LCDs that rendered the claims medically unnecessary and ineligible for payment. *Id.* at ¶¶6 and 11; *see generally* 42 C.F.R. § 410.38(d) (setting forth the conditions for Medicare payment of DME items like braces).

permitted under state law and are not prohibited by the Medicare conditions of payment.[8] Thus, to the extent the Indictment charges that Dr. Gupta did not perform a "medical examination," the law allows for such an exam to be done by telemedicine consultation. *See id.* at ¶4i. Simply put, any alleged deception about whether Dr. Gupta performed an in-person medical examination is not a condition of payment and not capable of influencing the payment decision.

Similarly, whether Dr. Gupta recommended to the patient that he or she continue to follow up as part of an ongoing plan of care is not a condition of payment under the Medicare regulations and has no bearing on the payment decision. Nothing in Chapter 5 of the applicable Medicare Program Integrity Manual (concerning DME), or elsewhere, required that the prescribing physician recommend that the patient consult with a pain management specialist as conditions for coverage. All that is required besides a written order and proof of delivery of the DME item, which are not in dispute here, is "sufficient documentation of the ***patient's medical condition*** to substantiate the necessity for the type and quantity of items ordered."

[8] New Jersey law permits telemedicine consultations as long as the provider has obtained identifying information from the patient, discloses the provider's identity and reviews the patient's medical history. *See* N.J. STAT. ANN. § 45:1-62(a). None of these requirements are at issue here. The statute specifically provides that a health care provider is not subject to any disciplinary action solely on the basis that the provider engaged in telemedicine or telehealth. *Id.* at § 45:1-62(h). Similarly, the Medicare regulations do not require face-to-face patient encounters to prescribe the braces at issue here. See *supra* at pgs. 9-10.

Section 5.7 (2019) (emphasis added).[9] Here, there is no specific allegations that the medical documentation of the patient's condition did not otherwise warrant brace prescriptions for any patient. The alleged false statements in the documentation about Dr. Gupta providing a recommendation to see a pain management specialist are not statements about the "patient's medical condition." Because these allegedly false statements could not influence any reimbursement decision, they were not material and cannot be actionable as fraud under any criminal statute.[10]

More importantly, the Indictment does not charge with any specificity that the so-called "fraudulent documents" were designed to cause Medicare any economic harm.

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[9] As CMS's website explains, CMS's program manuals are its "program issuances, day-to-day operating instructions, policies, and procedures that are based on statutes, regulations, guidelines, models, and directives" and which are used by "CMS program components, providers, contractors, Medicare Advantage organizations and state survey agencies . . . to administer CMS programs." Internet-Only Manuals, CMS, *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs.

The applicable version of the Medicare Program Integrity Manual in effect on or around March 2019 is available at: https://wayback.archive-it.org/2744/20161102133258/https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c05.pdf.

[10] In Count IV (for false statements relating to health care matters), the Indictment alleges that Dr. Gupta's brace prescriptions for the Medicare beneficiary "J.W." falsely stated that (a) the braces were medically necessary; (b) Dr. Gupta performed a "medical examination" on J.W.; (c) Dr. Gupta discussed J.W.'s back pain with J.W.; (d) Dr. Gupta heard the Medicare beneficiary, J.W. describe her back pain as "throbbing"; and (e) Dr. Gupta recommended that J.W. consult with a pain management physician. Indict. at ¶11. As already explained, the first and second alleged false statements ((a) and (b)) are again based on the erroneous LCD Fraud theory, and the last alleged false statement ((e)) is not material. And thus, the exact same fatal flaws that permeate the rest of the Indictment also permeate Count IV. As for the third and fourth alleged false statement ((c) and (d)), the defense recognizes that the Court cannot consider factual disputes in the context of the instant motion to dismiss. However, Dr. Gupta has a strong factual defense to these allegations as: (c) the audio recording of Dr. Gupta's consultation with J.W. proves that Dr. Gupta did, in fact, discuss J.W.'s back pain with her, and (d) Dr. Gupta's prescriptions nowhere state that he personally "heard" J.W. state that her back pain was "throbbing."

See Indict. at ¶4h. It does not allege that Dr. Gupta did not evaluate the patient's medical condition by failing to review the patient medical history and condition, and speak to the patient via telephone, or that the braces were not otherwise provided to the patients. Although the Indictment generally alleges that Dr. Gupta caused the submission of $5.4 million of brace claims that were medically unnecessary, it provides no notice why any prescription was medically unnecessary or what specific facts were misrepresented in the clinical documentation, other than that Dr. Gupta recommended to the patient that that he or she "continue medical follow-up as part of an ongoing plan of care." *Id.* at ¶4i. This failure to link this precise deceptive conduct as intending to cause monetary harm is fatal because the fraud statutes are designed to protect against only deprivations of money or property. *See McNalley v. United States*, 483 U.S. 350 (1987); *United States v. Riley*, 621 F.3d 312, 328 (3d Cir. 2010). Simply put, like *McNalley*, there are no specific facts alleged to show that the so-called deceptive conduct was intended to cause Medicare to lose of any money or property. *McNalley*, *supra*, 483 U.S. at 360. The misrepresentations, although allegedly deceitful, are not designed to and cannot cause any economic harm to Medicare because they do not affect the reimbursability of the braces and, therefore, cannot serve as a basis for a healthcare fraud prosecution. *See Starr*, 816 F.2d at 98; *Riley*, 621 F.3d at 328.

E. THE HEALTHCARE FRAUD STATUTE TOGETHER WITH THE BINDING MEDICARE REGULATIONS FAIL TO GIVE FAIR NOTICE THAT FAILURE TO CONDUCT AN IN-PERSON EXAMINATION OF A PATIENT TO PRESCRIBE BRACES CONSTITUTES FRAUD

Given that LCD 33318 only applies to knee braces, the Government must predicate its fraud theory for other braces on expert medical opinion that an in-person physical examination is the standard of care. But a mere disagreement about the standard of care and a patient's medical need cannot form the basis of a criminal fraud charge.

1. The Legislative History Shows That Congress Did Not Intend the Term "Defraud" to Apply to the Exercise of Medical Judgment.

Section 1347 was never intended to criminalize attempts to provide legitimate medical care to patients, regardless of whether other physicians would disagree with the medical need for treatment or the standard of care. As applied here, that is what Counts 1-3 attempt to do.

The Supreme Court has "traditionally exercised restraint in assessing the reach of a federal criminal statute, both out of deference to the prerogative of Congress, and out of concern that a fair warning should be given to the world in language that a common world will understand, of what the law intends to do if a certain line is passed." *Arthur Andersen LLP v. United States*, 544 U.S. 696, 703 (2005) (internal citations omitted). That restraint is "particularly appropriate . . . where the act underlines the conviction . . . is by itself innocuous,"—such as the provision of medical care to a geriatric patient. *Id.* "And, when interpreting a criminal statute that does not explicitly reach the conduct in question, we are reluctant to base an expansive reading on inferences drawn from subjective and variable 'understandings.'" *Williams v. United States*, 458 U.S. 279, 286 (1982).

Section 1347 is silent on whether the term "defraud" includes seeking reimbursement for the provision of medical services to real patients suffering from real illnesses—activities that are not traditionally considered as fraudulent conduct. *See Bond v. United States*, 572 U.S. 844, 860 (2014) (looking to legislative intent when the "general definition" of a term "defined extremely broadly" did not provide a clear statement of Congress' intent as to the reach of the statute); *see also Yates v. United States*, 574 U.S. 528, 535-37 (2015) (rejecting the Government's "unrestrained reading" of the phrase "tangible object" in a statute designed to address financial fraud when the Government prosecuted a fisherman for not preserving fish). But the statutory context and legislative history make clear that Congress did not intend the term "defraud" in

Section 1347 to apply to disagreements about medical judgment inherent in the treatment of a patient even if the treatment departed from orthodox practices that other physicians might employ. This was made explicit in the House Conference Report, which stated:

> There has been significant concern regarding the impact of the anti-fraud provisions on the practice of complementary and alternative medicine and healthcare. The practice of complementary, alternative, innovative, experimental, or investigational medical or health care itself will not constitute fraud. The conferees intend that this proposal not be interpreted as a prohibition of the practice of these types of medical or health care. ***The act is not intended to penalize a person who exercises a healthcare treatment choice or makes a medical or health care judgment in good faith simply because there is a difference of opinion regarding the form of diagnosis or treatment.***

H.R. Rep. No. 104-736 at 258 (1996), Conf. Rep. (1996 U.S.C.C.A.N. 1990, 2071) (emphasis added). Thus, Congress expressed its clear intent not to prevent innovative or non-traditional health care or otherwise good faith medical treatment and added the "knowingly and willfully" requirement to the offense as well.

By excluding an exercise of physicians' medical judgment from the scope of Section 1347, Congress showed that it intended the statute to be used for another purpose: to prosecute fraudulent conduct in the healthcare field as the concept of fraud is typically defined (*i.e.*, for doctors submitting claims when they provided no services, misrepresenting the extent of the services provided, or abdicating all medical judgment and issuing standing orders for treatment of patients with no medical conditions or whose medical histories and conditions have not been reviewed).

Applying the term "to defraud" to prohibit the exercise of medical judgment in the telehealth context would undermine Congress' efforts to preserve a patient's right to treatment and the doctor's ability to treat the patient. In stating that Section 1347 was not intended to reach

disagreements about medical judgment, Congress recognized that physicians needed freedom to make those judgments in the best interest of patients with very individualized circumstances and in uncertain and evolving medical fields. Congress emphasized that point in the very first provision of the Medicare statute:

> ***Nothing in this subchapter shall be construed to authorize any federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided***, or over the selection, tenure, or compensation of any officer or employee of any institution, agency, or person providing healthcare services; or to exercise any supervision or control over the administration or operation of any such institution, agency, or person.

42 U.S.C. § 1395 (emphasis added). By prosecuting a doctor for prescribing braces to geriatric patients after a medical evaluation, *i.e.*, a review of a patient's medical history and consultation by phone, the Indictment seeks to do exactly what Section 1395 prohibits: "Exercise any supervision or control over the practice of medicine or the manner in which medical services are provided." The law accepts that it is important to allow medical professionals to exercise their medical judgment based on their experience and that it is inappropriate to force medical professionals to follow bright-line rules for medical treatment set by either the Government or insurance companies. *See Kent v. Provident Life & Cas. Ins. Co.*, 146 F. App'x 862, 864 (9th Cir. 2005) (rejecting an attempt by an insurance company to disregard cardiologists' opinions that a cardiac patient was at risk of developing "serious heart problems" because those opinions were not supported by large well-designed studies and reasoning that cardiologists "often have no choice but to make well-considered decisions regarding the management of a patient's care in the absence of 'large, well-designed prospective studies'" and that "[s]uch exercise of expert medical judgment, based on a doctor's own experience and the patient's past history is particularly necessary when patients' lives are at stake"); *Weaver v. Reagen*, 886 F.2d 194, 199

(8th Cir. 1989) (rejecting state Medicaid's decision to confine doctors to restrictive criteria for prescribing a drug because "[t]he decision of whether or not certain treatment or a particular type of surgery is 'medically necessary' rests with the individual recipient's physician and not with clerical personnel or Government officials"). If Section 1395 restricts the civil and administrative powers of Government officials to regulate a physician's choice of treatment in the exercise of medical judgment, then it must follow that the statute's criminal fraud provision may not be deployed for this purpose. Congress never intended to restrict the exercise of a physician's medical judgment in caring for real-life patients and never envisioned that federal prosecutors could decree a wooden rule that no brace could be prescribed without an in-person physical examination based only on the disagreement between medical professionals on the standard of care.

2. Section 1347 as Applied Fails to Provide Fair Notice of What Is Prohibited.

To the extent that the Government intends to prosecute Dr. Gupta for violating the standard of care as opined upon by a Government expert, Section 1347, as applied, violates the Due Process clause. "A conviction fails to comport with due process if the statute under which it is obtained fails to provide a person of ordinary intelligence fair notice of what is prohibited or is so standardless that it authorizes or encourages seriously discriminatory enforcement." *Holder v. Humanitarian Law Project*, 561 U.S. 1, 18 (2010). To the extent this prosecution is based on an expert opinion that the medical standard of care prohibits the brace prescriptions without an in-person physical examination, it violates Due Process in each of these two independent respects: (1) physicians of ordinary intelligence are not provided fair notice that their choice of medical treatment falls so far outside acceptable criteria that it is criminal and fraudulent to seek reimbursement for such treatment; and (2) the Government's attempt to criminalize departures

from medical standards is so standardless that it permits seriously discriminatory enforcement. Neither Section 1347 itself nor any of the controlling Medicare regulations provides fair notice to physicians because the concept of "medical necessity" in healthcare procedures is nowhere defined, and the implementing regulations permit a physician to prescribe braces by exercising medical judgment through a review of medical history and telephone patient consultations. *See supra* Section II.C. The Supreme Court has already observed that a statute prohibiting treatment without a "legitimate medical purpose" to be ambiguous. *Gonzales v. Oregon*, 546 U.S. 243, 258 (2006) ("All would agree . . . that the statutory phrase 'legitimate medical purpose' is a generality, susceptible to more precise definition and open to varying construction and thus ambiguous in the relevant sense."). And in the context of medical treatment, the Supreme Court has always emphasized the importance of criminal statutory provisions concerning medical care being "interpreted to allow the physician to make his determination in the light of all attendant circumstances—psychological and emotional as well as physical—that might be relevant to the well-being of the patient." *Colautti v. Franklin*, 439 U.S. 379, 394 (1979); *see also Doe v. Bolton*, 410 U.S. 179, 192 (1973). In *Colautti*, the Court criticized, on vagueness grounds, statutes that do "not afford broad discretion to the physician," but instead attempt to "condition [] potential criminal liability on confusing and ambiguous criteria" and "therefore present [] serious problems of notice, discriminatory application, and chilling affect on the exercise of

constitutional rights." *Colautti*, 439 U.S. at 394.[11] While a number of courts have upheld the constitutionality of the Section 1347 against a general vagueness challenge, those cases presented different and far more egregious facts, such as a doctor falsely certifying that stents he placed in arteries with little or no blockage were reasonable and necessary and because the doctor acknowledged the 70% occlusion standard. *See United States v. McClean*, 715 F.3d 129, 136-37 n.6. (4th Cir. 2013).[12]

Here, to the extent that the Government predicates a finding of fraud on its expert's opinion that the medical standard of care always requires a physician to examine a patient in person before prescribing a brace, no fair notice can be discerned by the medical community. Such expert testimony is particularly problematic given that the state laws, including New

[11] In *Colautti*, the Court invalidated two Pennsylvania statutory provisions on vagueness grounds. One provision imposed criminal liability on a physician who performs an abortion without determining whether the fetus is viable or "if there is sufficient reason to believe that the fetus may be viable" *Id.* at 390-97. Another provision imposed criminal liability on any physician who, after determining the fetus is viable or may be viable, fails to exercise the degree of professional skill, care, and diligence necessary to preserve the life of the fetus. *Id.* at 397-401. In each instance, the Court based its ruling on the statutory ambiguity and lack of a scienter requirement, but also expressed worry about attempts to criminalize a physician's efforts to operate in areas of "complex medical judgment about which experts can—and do—disagree." *Id.* at 401.

[12] In *McClean* there was proof that the doctor made misrepresentations to patients, recorded symptoms that the patients did not experience and told a patient that he placed a stent in an unblocked artery "because it was easy." *Id.* at 139-40; *see also United States v. Patel*, 485 F. App'x 702 (5th Cir. 2012) (declining to decide whether the standard of "medical necessity" furnishes adequate notice beyond the facts of that case where the physician agreed there were concrete standards that he was on notice of). *United States v. Paulus*, 894 F.3d 267 (6th Cir. 2018), is not to the contrary. In that case, Paulus's conviction rested upon misrepresenting facts about the extent of blockages in arteries in order to justify unnecessary stenting procedures. *See id.* at 272-74. Here, the medical necessity rests solely upon a difference in opinion of whether a patient can be diagnosed and treated with orthotic braces without an in-person medical examination. As the court in *Paulus* noted, "the degree of stenosis [arterial blockage] *is* a fact capable of proof or disproof," and thus a "doctor who deliberately inflates the blockage he sees on an angiogram has told a lie." *Id.* at 275. No such material misrepresentation about the facts of the patient's medical condition exists here.

Jersey's, permit telehealth consultations and the binding Medicare regulations allow for prescriptions and payment of braces without in-person examinations. *See supra* at Section II.C. Medical necessity is not defined in the operative statute, and there is no discernable line that identifies when a medical judgment crosses over from non-criminal "necessary" to criminally "unnecessary." To base a criminal prosecution on a Government expert's opinion that the standard of care requires an in-person medical examination for brace prescriptions when the law permits telephonic consultations would not give "the attending physician the room he needs to make his best medical judgment." *Colautti*, 439 U.S. at 397 (original quotation marks and citation omitted). As the Sixth Circuit has explained, the determination of whether medical necessity exists is "fraught with uncertainty and susceptible to being disputed by others." *Womens Medical Professional Corporation v. Voinovich*, 130 F.3d 187, 205 (6th Cir. 1997) (striking down a criminal statute as unconstitutionally vague).

The Government's proposed expansion of Section 1347 to cover treatments that depart from some standard defined by its own experts of "medical necessity" also encourages discriminatory enforcement. Due Process requires that "a legislature establish minimal guidelines to govern law enforcement." *Kolender v. Lawson*, 461 U.S. 352, 358 (1983). Where there are no such minimal guidelines a statute violates Due Process because it permits "a standardless sweep [that] allows policemen, prosecutors, and juries to pursue their personal predilections." *Id.* (original quotation marks and citations omitted). This principle has been equally applied in the medical field. *See Forbes v. Napolitano*, 236 F.3d 1009, 1013 (9th Cir. 2000) (holding a statute unconstitutionally vague because it gives doctors no constructive notice and prosecutors "no standards to focus the statute's reach"). This unilateral discretion afforded to prosecutors is evident in this case, as many doctors who have worked with AffordADoc

prescribing braces by phone have not been prosecuted, and those who have been prosecuted have admitted that they did not review the patient histories or even speak with the patients as set falsely forth in the medical documentation. *See, e.g.*, Indict. at ¶5(g) (ECF 1), *United States v. DeCorso*, No. 19-cr-249 (D.N.J. Apr. 5, 2019) ("JOSEPH DECORSO . . . concealed and disguised the scheme by preparing or causing to be prepared false and fraudulent documentation . . . including documentation stating that JOSEPH DECORSO ***had 'discussion[s]' with Medicare beneficiaries*** and conducted various diagnostic tests prior to ordering DMEPOS, when, in fact, JOSEPH DECORSO ***rarely had a discussion with these Medicare beneficiaries*** and rarely conducted any diagnostic tests.") (emphasis added).

Because the Government has interpreted the healthcare fraud statute far beyond what Congress ever intended and in a way such that the Indictment conflicts with the existing Medicare regulations, the Indictment violates the Due Process Clause.

III. CONCLUSION

In sum, given that: (1) the Government's LCD Fraud theory conflicts with the Medicare laws that permit ordering braces based on telephone consults, and this baseless fraud theory otherwise permeates the entire Indictment; (2) the Indictment does not otherwise allege a material deception intending to cause economic harm or that is otherwise capable of influencing a payment decision; and (3) allowing the Government to proceed on a difference of medical opinion about the applicable standard of care deprives Dr. Gupta of Due Process in this case—Dr. Gupta respectfully requests that Counts 1-4 of the Indictment be dismissed as a matter of law.

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